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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/789,359 | 02/26/2004 | James H. Brauker | DEXCOM.037A | 5145 |

20995 7590 03/20/2008

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| EXAMINER | |
|---|---|
| BOUCHELLE, LAURA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3763 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 03/20/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/789,359 | BRAUKER ET AL. | |
| | Examiner | Art Unit | |
| | LAURA A. BOUCHELLE | 3763 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *15-25,27-30,32 and 34-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-25,27-30,32 and 34-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

### *Claim Rejections - 35 USC § 102*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 15-17, 22-24, 27, 28, 29, 30, 32, 34-36, 40-43, 45, 46, 49, 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Lord et al (US 5569186). Lord discloses a closed loop infusion pump system comprising a glucose sensor 16, a receiver 14 which receives data signals from the sensor (Col. 3, lines 2-4), and a delivery device 22 physically detachable connectable to the receiver. The device comprises a processor 28 configured to calculate and output delivery instructions and includes a validation module (Col. 4, lines 4-9). The device estimates glucose values responsive to glucose sensor data and host's metabolic response (Col. 2, lines 13-15).

3. Regarding claims 29 and 30, Gough et al (US 4703756), which Lord incorporates by reference, teaches an electrochemical glucose sensor which includes an enzyme membrane system for electrochemical detection of glucose.

### *Claim Rejections - 35 USC § 103*

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 18, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lord in view of Connelly et al (US 6589229). Claim 18 differs from Lord in calling for the delivery device to comprise a syringe. Claim 21 differs in calling or the delivery device to comprise a

pen or jet type injector. Connelly teaches that it is well known in the art to use syringes or pen type injectors to deliver insulin containing drugs to treat diabetes. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lord to include a syringe or pen type injector as taught by Connelly to deliver insulin to a diabetic patient.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lord in view of Mitragotri et al (US 5814599). Claim 19 differs from Lord in calling for the delivery device to comprise a transdermal patch. Mitragotri teaches the use of a transdermal patch to deliver insulin to a diabetic patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lord to include a transdermal patch to deliver insulin to a diabetic patient as taught by Mirtagotri as this is a well known method to administer insulin to a patient.

7. Claims 20, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lord in view of Mullins (US 3219533). Claims 20, 44 differ from Lord in calling for the delivery device to comprise an inhaler or spray delivery device. Mullins teaches an inhaler that sprays insulin for treating diabetic patents. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lord to include an inhaler that sprays insulin as taught by Mullins because it is a well know method to deliver insulin to a patient with diabetes.

8. Claims 25, 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lord in view of Dionne et al (US 6083523). Claim 25 differs from Lord in calling for a processor programmed to determine a host's metabolic response to cell tranplantation. Dionne teaches that

it is well known in the art to treat diabetes and the resulting decreased production of insulin by pancreatic islet cells by infusing the patient with beta islet cells (Col. 1, lines 15-26). Lord teaches measuring a host's metabolic response to a treatment. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lord to include the delivery of beta islet cells to a patient as taught by Dionne to treat the decrease in insulin production in a patient with diabetes.

9. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lord in view of Mann et al (US 7025743). Claim 47 differs from Lord in calling for the device to request information about meals, calories or carbohydrates. Mann teaches an infusion device for insulin that requests the input of carbohydrates so that the processor can determine the proper dose of insulin (Col. 23, lines 20-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lord to include a request of information about carbohydrates as taught by Mann so that the processor can accurately determine the insulin dosage.

10. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lord in view of Goode, Jr. et al (US 2005/0027180). Claim 48 differs from Lord in calling for the programming to comprise a pattern recognition algorithm. Goode teaches a system for processing analyte sensor data that includes a variety of algorithms that are capable of processing analyte data including a pattern recognition algorithm (Page 19, paragraph 0037). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lord to include a pattern recognition algorithm as taught by Goode because it is a well known algorithm for use with data processing.

***Response to Arguments***

11. Applicant's arguments filed 2/6/07 have been fully considered but they are not persuasive.

12. Applicant argues that Lord does not disclose a medicament delivery device physically connectable to the receiver. The examiner disagrees. As can be seen in Fig. 1, the medicament delivery device 22 is connectable to the receiver 14.

13. Applicant argues that Lord fails to teach a single point glucose monitor. The examiner points to the Gough (US 4703756) patent which is incorporated in the Lord patent by reference where a point glucose monitor is disclosed.

***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
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/L. A. B./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
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